

December 11, 2001

MEMORANDUM:

SUBJECT: Lindane (009001): Reregistration Case 0315. Revised Product and Residue Chemistry Chapters for the Lindane Reregistration Eligibility Document (RED). DP Barcode: D279259.

FROM: Thurston G. Morton, Chemist
Reregistration Branch 4
Health Effects Division (7509C)

THROUGH: Susan V. Hummel, Branch Senior Scientist
Reregistration Branch 4
Health Effects Division (7509C)

TO: Rebecca Daiss, Risk Assessor
Reregistration Branch 4
Health Effects Division (7509C)

And

Mark Howard/Betty Shackleford
Reregistration Branch 3
Special Review & Reregistration Division (7508C)

Attached are the revised Product and Residue Chemistry Chapters for the lindane RED. The chapters were assembled by Dynamac Corporation under supervision of HED. The data assessment has undergone secondary review in the branch and has been revised to reflect branch policies. This memorandum serves to update the Product and Residue Chemistry Chapter (T. Morton, 6/7/01, D274754) by incorporating comments from the public comment period and incorporating submissions reviewed by the Agency since 9/26/00. Only uses supported for reregistration by Inquinosa are included.

EXECUTIVE SUMMARY:

Product Chemistry

- C Pertinent product chemistry data remain outstanding for the Inquinosa 99.5% T/TGAI concerning product identity, starting materials and production process, preliminary analysis, certified limits, oxidation/reduction, explodability, storage stability, corrosion characteristics, and UV/visible absorption (OPPTS 830.1550, 1600, 1620, 1700, 1750, 6314, 6316, 6317, 6320, and 7050). Technical products registered to Kanoria Chemicals & Industries were suspended effective 12/5/00 for failure to comply with a cost sharing agreement with Inquinosa. Therefore, all technical products registered which are repackages of the Kanoria products would be required to change suppliers. The Prentiss, Drexel, and Amvac 99.5% Ts are repackaged from EPA-registered products, and all data requirements will be satisfied by data for the technical source products. Provided that the registrants submit the data required in the attached data summary tables for the lindane T/TGAIs, and either certify that the suppliers of beginning materials and the manufacturing processes have not changed since the last comprehensive product chemistry reviews or submit complete updated product chemistry data packages, the Branch has no objections to the reregistration of lindane with respect to product chemistry data requirements.

Residue Chemistry

- C The Agency will not require a new confined rotational crop study provided the registrants propose a 30-day plantback interval for leafy vegetables and a 12-month plantback interval for all other unregistered crops on all of their end-use product labels for lindane. The registrants have informed the Agency they will propose the specified plantback intervals.
- C A new nature of the residue study is required for application of lindane as a seed treatment to a cereal grain.
- C If the HED Metabolism Assessment Review Committee determines the residues of concern to include metabolites in addition to lindane, then additional crop field trial data, magnitude of the residue in poultry and cattle, and processing studies are required. In addition, an adequate residue analytical method and storage stability data will be required.

Dietary Exposure/Risk Assessment

- C Anticipated residues (DP Barcode D279260, T. Morton, 12/4/01) will be provided for all commodities and should be used when calculating the dietary risk associated with the RED. Although the database for lindane is substantially complete, additional data are needed to eliminate the uncertainties associated with the exposure/risk assessment. The anticipated residue values are the best estimates HED can provide using the residue data available at the time of the RED. These values have an inherent uncertainty associated with variations in analytical methods, geographical representation of field trials, seasonal variation of residue levels, use of TRR from metabolism studies, etc.

cc : Chem F, Chron F. Morton , Shallal

RDI:ChemSAC: 9/13/00; SVH:12/11/01

TM, Thurston Morton, Rm. 816D CM2, 305-6691, mail code 7509C

LINDANE
Case 0315; PC Code 009001
D279259

Reregistration Eligibility Decision:
Product Chemistry Considerations

December 11, 2001

Contract No. 68-W-99-053

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA

Submitted by:
Dynamac Corporation
2275 Research Boulevard
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LINDANE

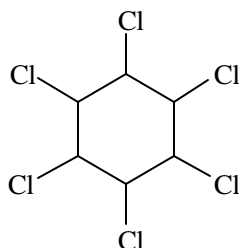
REREGISTRATION ELIGIBILITY DECISION:

PRODUCT CHEMISTRY CONSIDERATIONS

Case No. 0315; PC Code 009001

DESCRIPTION OF CHEMICAL

Lindane (gamma isomer of benzene hexachloride, gamma isomer of hexachlorocyclohexane) is a broad-spectrum organochlorine insecticide/acaricide registered for control of insects and other invertebrates. The only registered food/feed use is seed treatment for field and vegetable crops.



Empirical Formula:	C ₆ H ₆ Cl ₆
Molecular Weight:	290.9
CAS Registry No.:	58-89-9
PC Code:	009001

IDENTIFICATION OF ACTIVE INGREDIENT

Lindane is a white crystalline solid with a melting point of 112-113 C, specific gravity of 1.85, octanol/water partition coefficient (K_{ow}) of 3135, and vapor pressure of 9.4 x 10⁻⁶ mm Hg at 20 C. Lindane is soluble in water (10 ppm at 20 C) and most organic solvents, including acetone and aromatic and chlorinated hydrocarbons. Lindane is only slightly soluble in mineral oils. Lindane is stable to light, heat, air, and strong acids, but decomposes upon exposure to trichlorobenzenes and HCl in alkali.

MANUFACTURING-USE PRODUCTS

According to a search of the Reference Files System (REFS) conducted 5/29/01, there are eight registered manufacturing-use products (MPs) under PC Code 009001. The registered MPs subject to a reregistration eligibility decision are listed in Table 1.

Table 1. Registered lindane manufacturing-use products.

Formulation	EPA Registry Number	Registrant
99.5% T	655-28 ¹	Prentiss Incorporated
99.5% T	655-393 ¹	
99.5% T	5481-225 ¹	Amvac Chemical Corporation
99.5% T	19713-61 ¹	Drexel Chemical Company
99.5% T	19713-191 ¹	
99.5% T	40083-1	Inquinosa Internacional, S.A.
99.5% T	66951-1	Kanoria Chemicals & Industries Ltd.
99.5% T	66951-2	

¹ Repackaged from an EPA-registered product.

REGULATORY BACKGROUND

The Lindane Reregistration Standard and the Addendum to the Lindane Reregistration Standard were issued 6/7/85 and 7/16/85, respectively, and required additional product chemistry data concerning lindane. The Lindane Guidance Document dated 9/85 reiterated the data gaps outlined under the Addendum to the Reregistration Standard. Data submitted in response to the Guidance Document for the lindane T/TGAIs were evaluated in the Lindane Reregistration Standard Update dated 1/31/91 with regard to adequacy in fulfilling product chemistry requirements. The Centre International d'Etudes du Lindane (CIEL) members (Rhone-Poulenc, Inc., EM Industries, Inc. (representing Celamerck GmbH and Company), and Inquinosa) have submitted data jointly. Kanoria Chemicals and Industries, Inc. became a member of CIEL in 1994 (Letter from McKenna and Cuneo on behalf of CIEL dated 11/30/94, in support of application to register a technical lindane product). Prentiss and Amvac previously entered into data sharing agreements with CIEL in accordance with the provisions of FIFRA §3(C)(2)(B)(ii). Technical products registered to Kanoria Chemicals & Industries were suspended effective 12/5/00 for failure to comply with a cost sharing agreement with Inquinosa.

The current status of the product chemistry data requirements for the lindane T/TGAIs is presented in the attached data summary tables. Refer to these tables for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

Pertinent product chemistry data remain outstanding for the Inquinosa 99.5% T/TGAI concerning product identity, starting materials and production process, preliminary analysis, certified limits, oxidation/reduction, explodability, storage stability, corrosion characteristics, and UV/visible absorption (OPPTS 830.1550, 1600, 1620, 1700, 1750, 6314, 6316, 6317, 6320, and 7050). Technical products registered to Kanoria Chemicals & Industries were suspended effective 12/5/00 for failure to comply with a cost sharing agreement with Inquinosa. Therefore, all technical registered which are repackages of the Kanoria products would be required to change suppliers. The Kanoria products are shown in attached data summary tables for informational purposes only. The Prentiss, Drexel, and Amvac 99.5% Ts are repackaged from EPA-registered products, and all data requirements will be satisfied by data for the technical source products. Provided that the registrants submit the data required in the attached data summary tables for the lindane T/TGAIs, and either certify that the suppliers of beginning materials and the manufacturing processes have not changed since the last comprehensive product chemistry reviews or submit complete updated product chemistry data packages, HED has no objections to the reregistration of lindane with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

DP Barcode: D211047
Subject: RD Product Chemistry Review for EPA File Symbol Number 66951-R, Kanoria Lindane Crystals
From: S. Mathur
To: G. Larocca
Dated: 3/21/95
MRID(s): 43498201-43498203

DP Barcode: D211063
Subject: RD Product Chemistry Review for EPA File Symbol Number 66951-E, Kanoria Lindane Powder
From: S. Mathur
To: G. Larocca
Dated: 3/21/95
MRID(s): 43498201-43498203

PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

References (cited):

00072468 Hooker Chemical & Plastics Corporation (19??) Product Chemistry Data: Lindane HGI. (Unpublished study received May 7, 1981 under 935-17; CDL:245029-A)

00102995 Zoecon Corp. (1981) [Study of the Chemical Lindane]. (Compilation; unpublished study received Sep 15, 1981 under 20954-107; CDL:246026-A)

00118712 Commerce Industrial Chemicals, Inc. (1969) Laboratory Report: [Lindane]: Lab No. C11,131, Supplement #1. (Unpublished study received May 12, 1969 under 10531-1; submitted by Petland Products, Inc., Chicago, IL; CDL:026276-A)

00118743 Makhteshim Beer-Sheva Chemical Works, Ltd. (1976) [Chemistry of Lindane]. (Compilation; unpublished study received Jul 11, 1978 under 11678-16; CDL:234441-A)

00160127 Inquinsa (19??) Synthesis of Lindane. Unpublished study. 4 p.

00160129 Buys, M. (1986) Lindane...Product Identity and Composition... Discussion of the Formation of Impurities: Report AG/CRLD/AN/MB/ID/15274.86. Unpublished study prepared by Rhone-Poulenc Agrochimie. 10 p.

00160130 Mirfakhrae, K.; Norris, F. (1986) Determination of the Octanol/Water Partition Coefficient of Lindane: Ref. No. 86/BHL/191/AG:ASD No. 86/187. Unpublished study prepared by Rhone-Poulenc Inc. 26 p.

00164782 Viziere, G. (1986) Lindane: Analysis and Certification of Product Ingredients: AG/CRLD/AN/MB/ID/15871.86. Unpublished study prepared by Rhone-Poulenc Agrochimie. 57 p.

00164783 Buys, M. (1986) Lindane: Analytical Data for the Technical Grade Lindane Produced by Inquinsa: Report AG/CRLD/AN/MB/ID/158874.86. Unpublished study prepared by Rhone-Poulenc Agrochimie. 9 p.

43498201 Brookman, D.; Curry, K. (1994) The Product Chemistry of Kanoria Lindane (Product Identity and Disclosure of Ingredients). Unpublished study prepared by Technology Sciences Group, Inc. 35 p.

43498202 Brookman, D.; Curry, K. (1994) The Product Chemistry of Kanoria Lindane (Analysis and Certification of Product Ingredients). Unpublished study prepared by Technology Sciences Group, Inc. 49 p.

43498203 Brookman, D.; Curry, K. (1994) The Product Chemistry of Kanoria Lindane (Physical and Chemical Characteristics). Unpublished study prepared by Technology Sciences Group, Inc. 18 p.

Case No. 0315
PC Code: 009001

Case Name: Lindane
Registrant: Prentiss, Inc.
Product(s): 99.5% Ts (EPA Reg. Nos. 655-28 and 655-393)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.1550	Product identity and composition	Y	CSF 4/21/97 (655-28) CSF 4/23/97 (655-393)
830.1600	Description of materials used to produce the product	N/A	
830.1620	Description of production process	N/A	
830.1670	Discussion of formation of impurities	N/A	
830.1700	Preliminary analysis	N/A	
830.1750	Certified limits	Y	CSF 4/21/97 (655-28) CSF 4/23/97 (655-393)
830.1800	Enforcement analytical method	N/A	
830.6302	Color	N/A	
830.6303	Physical state	N/A	
830.6304	Odor	N/A	
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	N/A	
830.6314	Oxidation/reduction: chemical incompatibility	N/A	
830.6315	Flammability	N/A	
830.6316	Explosibility	N/A	
830.6317	Storage stability	N/A	
830.6319	Miscibility	N/A	
830.6320	Corrosion characteristics	N/A	
830.7000	pH	N/A	
830.7050	UV/visible absorption	N/A	
830.7100	Viscosity	N/A	
830.7200	Melting point/melting range	N/A	
830.7220	Boiling point/boiling range	N/A	
830.7300	Density/relative density/bulk density	N/A	
830.7370	Dissociation constants in water	N/A	
830.7550	Partition coefficient (n-octanol/water), shake flask method	N/A	
830.7840	Water solubility: column elution method; shake flask method	N/A	
830.7950	Vapor pressure	N/A	

¹ Y = Yes; N = No; N/A = Not Applicable. The Prentiss technical products are repackaged from EPA-registered products; data requirements will be satisfied by data for the source products.

² The CSFs were obtained from the product jackets.

Case No. 0315
PC Code: 009001

Case Name: Lindane
Registrant: Amvac Chemical Corp.
Product(s): 99.5% T (EPA Reg. No. 5481-225)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.1550	Product identity and composition	N ³	CSF 6/19/86
830.1600	Description of materials used to produce the product	N/A	
830.1620	Description of production process	N/A	
830.1670	Discussion of formation of impurities	N/A	
830.1700	Preliminary analysis	N/A	
830.1750	Certified limits	N ³	CSF 6/19/86
830.1800	Enforcement analytical method	N/A	
830.6302	Color	N/A	
830.6303	Physical state	N/A	
830.6304	Odor	N/A	
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	N/A	
830.6314	Oxidation/reduction: chemical incompatibility	N/A	
830.6315	Flammability	N/A	
830.6316	Explosibility	N/A	
830.6317	Storage stability	N/A	
830.6319	Miscibility	N/A	
830.6320	Corrosion characteristics	N/A	
830.7000	pH	N/A	
830.7050	UV/visible absorption	N/A	
830.7100	Viscosity	N/A	
830.7200	Melting point/melting range	N/A	
830.7220	Boiling point/boiling range	N/A	
830.7300	Density/relative density/bulk density	N/A	
830.7370	Dissociation constants in water	N/A	
830.7550	Partition coefficient (n-octanol/water), shake flask method	N/A	
830.7840	Water solubility: column elution method; shake flask method	N/A	
830.7950	Vapor pressure	N/A	

¹ Y = Yes; N = No; N/A = Not Applicable. The available CSF indicates that the Amvac technical product is repackaged from EPA-registered products which have been canceled (1/28/98). If the product is repackaged from a currently registered product, data requirements will be satisfied by data for the source product; otherwise, additional product chemistry data may be required.

² The CSF was reviewed in the Lindane Reregistration Standard Update dated 1/31/91.

³ The CSF must be revised to cite the current registered source(s) of the technical product (PPIS Deficiency Notice, 11/1/99, J. Hinkle).

Case No. 0315
PC Code: 009001

Case Name: Lindane
Registrant: Drexel Chemical Company
Product(s): 99.5% Ts (EPA Reg. Nos. 19713-61 and 19713-191)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.1550	Product identity and composition	Y	CSFs 2/25/98
830.1600	Description of materials used to produce the product	N/A	
830.1620	Description of production process	N/A	
830.1670	Discussion of formation of impurities	N/A	
830.1700	Preliminary analysis	N/A	
830.1750	Certified limits	Y ³	CSFs 2/25/98
830.1800	Enforcement analytical method	N/A	
830.6302	Color	N/A	
830.6303	Physical state	N/A	
830.6304	Odor	N/A	
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	N/A	
830.6314	Oxidation/reduction: chemical incompatibility	N/A	
830.6315	Flammability	N/A	
830.6316	Explosibility	N/A	
830.6317	Storage stability	N/A	
830.6319	Miscibility	N/A	
830.6320	Corrosion characteristics	N/A	
830.7000	pH	N/A	
830.7050	UV/visible absorption	N/A	
830.7100	Viscosity	N/A	
830.7200	Melting point/melting range	N/A	
830.7220	Boiling point/boiling range	N/A	
830.7300	Density/relative density/bulk density	N/A	
830.7370	Dissociation constants in water	N/A	
830.7550	Partition coefficient (n-octanol/water), shake flask method	N/A	
830.7840	Water solubility: column elution method; shake flask method	N/A	
830.7950	Vapor pressure	N/A	

¹ Y = Yes; N = No; N/A = Not Applicable. The Drexel technical products are repackaged from EPA-registered products; data requirements will be satisfied by data for the source products. Data previously submitted by Drexel in support of the reregistration of these products are no longer applicable.

² The CSFs were obtained from the product jackets.

³ The CSFs should be revised to propose certified limits for the active ingredient which reflect the actual levels in the technical products.

Case No. 0315
PC Code: 009001

Case Name: Lindane
Registrant: Inquinosa Internacional, S.A.
Product(s): 99.5% Ts (EPA Reg. No. 40083-1)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.1550	Product identity and composition	N ³	
830.1600	Description of materials used to produce the product	N ⁴	00160127
830.1620	Description of production process	N ⁵	00160127
830.1670	Discussion of formation of impurities	Y	00160129
830.1700	Preliminary analysis	N ⁶	00164783
830.1750	Certified limits	N ³	
830.1800	Enforcement analytical method	Y ⁷	00164782
830.6302	Color	Y	00072468
830.6303	Physical state	Y	00118743
830.6304	Odor	Y	00102995
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	00072468
830.6314	Oxidation/reduction: chemical incompatibility	N	
830.6315	Flammability	N/A ⁸	
830.6316	Explosibility	N	
830.6317	Storage stability	N	
830.6319	Miscibility	N/A ⁸	
830.6320	Corrosion characteristics	N	
830.7000	pH	N/A ⁹	
830.7050	UV/visible absorption	N ¹⁰	
830.7100	Viscosity	N/A ⁸	
830.7200	Melting point/melting range	Y	00118743
830.7220	Boiling point/boiling range	N/A ⁸	
830.7300	Density/relative density/bulk density	Y	00072468
830.7370	Dissociation constants in water	N/A ⁹	
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	00160130
830.7840	Water solubility: column elution method; shake flask method	Y	00118712
830.7950	Vapor pressure	Y	00118743

¹ Y = Yes; N = No; N/A = Not Applicable. A CSF for the Inquinosa technical product was not available from the product jacket. Until a current CSF is available for comparison, the Agency cannot ascertain whether TGAI data (physical/chemical data) from other CIEL members are applicable to the Inquinosa product.

² **Bolded** references were reviewed in the Lindane Reregistration Standard dated 6/7/85 and all other references were reviewed in the Lindane Reregistration Standard Update dated 1/31/91.

³ An updated CSF is required for evaluation of the product chemistry data (Lindane Reregistration Standard Update dated 1/31/91).

⁴ Information is required concerning the relative amounts and order in which the starting materials are added.

⁵ Additional information is required concerning: (i) clarification as to whether the process is a batch or continuous process; (ii) the duration of each step and the entire process; (iii) description of the equipment used; and (iv) quality control measures used to ensure the integrity of the product.

⁶ Data demonstrating that the method used for analysis of dioxins and dibenzofurans can quantitate the 2,3,7,8-TCDD reference standard to 0.1 ppb must be provided.

⁷ If the CIPAC normalized 4 gamma/1/M/1 cryoscopic method is to be used for enforcement of certified limits of the active ingredient, then a complete description of the method, along with supporting validation data, is required.

⁸ Data are not required because the TGAI/MP is a solid at room temperature.

⁹ Data were not required by the Lindane Registration Standard concerning pH and dissociation constant.

¹⁰ The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

LINDANE
Case 0315; PC Code 009001
D279259

Reregistration Eligibility Decision
Residue Chemistry Considerations

December 11, 2001

Contract No. 68-W-99-053

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA

Submitted by:
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LINDANE

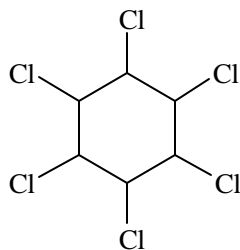
REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

Case 0315; PC Code 009001

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LINDANE



REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

Case 0315; PC Code 009001

INTRODUCTION

Lindane (gamma isomer of benzene hexachloride, gamma isomer of hexachlorocyclohexane) is a broad spectrum organochlorine insecticide/acaricide registered for control of insects and other invertebrates on a wide variety of field crops and vegetable crops (seed treatment only). According to a REFS search, conducted on 5/29/01, there are approximately 34 federally registered end-use products (EPs) containing lindane as the active ingredient and three Section 24C registrations. Lindane end-use products are formulated as dust (D), wettable powder (WP), emulsifiable concentrate (EC), flowable concentrate (FIC), and ready-to-use (RTU) solution.

The reregistration of lindane is being supported by Centre International d'Etudes du Lindane (CIEL) and its member company holding U.S. registrations, Inquinsa, S.A. Currently, Inquinsa does not have any registered lindane end-use products. In 1993, CIEL offered to voluntarily cancel all crop uses of lindane except seed treatment and certain non-food uses. The Agency considers lindane seed treatment as a food use requiring tolerances based on existing data from radiolabeled studies indicating uptake of residues from the treated seeds into the aerial portion of the growing crop.

REGULATORY BACKGROUND

Lindane is a List A reregistration pesticide. A Reregistration Standard for Lindane was issued 9/85. The Residue Chemistry Chapter to the Reregistration Standard was issued on 6/7/85, an addendum on 9/5/85, and an Update on 1/31/91. The Reregistration Standard along with its Science Chapters summarized the available data for each residue chemistry guideline and specified what additional data are required for reregistration purposes. Data Call-In (DCI) Notices for lindane were issued by the Agency on 9/30/91, 3/3/95, 10/13/95, and 3/31/97. The information contained in this document outlines the current Residue Chemistry Science Assessments with respect to supporting seed treatment uses of lindane, as well as the reregistration of the pesticide.

In 1983, EPA concluded a major Special Review effort of lindane based on carcinogenicity, fetotoxicity/teratogenicity, reproductive effects, and acute effects on aquatic organisms. This effort resulted in the cancellation of indoor uses of smoke fumigation devices and greatly limited the use of pet dips on dogs. In addition, there were uses that were allowed to continue only if certain imposed restrictions were implemented. The restrictions were based on the degree of associated hazards, and included changes in warning labels, the wearing of protective clothing, and restrictions to limit uses to certified pest control operators.

In 1995, EPA announced (FR Vol. 60, No. 143, 38329-38331, 7/26/95) its decision not to initiate a Special Review of lindane based on worker health concerns arising from studies showing irreversible renal effects in the rat. The Agency has determined that these effects occur only in the kidneys of male rat and are not relevant for human risk assessment.

Tolerances are currently established under 40 CFR §180.133 for residues of lindane *per se* in/on various raw agricultural commodities at 0.01 ppm (pecans) to 3 ppm (cucumbers, lettuce, melons, mushrooms, pumpkins, squash, summer squash, and tomatoes). Lindane tolerances are also established at 4 ppm in the fat of meat from hogs and at 7 ppm in the fat of meat from cattle, goats, horses, and sheep. No tolerances have been established for processed food/feed commodities. Adequate methods are available for the enforcement of tolerances for residues of lindane *per se* in/on plant and animal commodities.

SUMMARY OF SCIENCE FINDINGS

GLN 860.1200: Directions for Use

The basic registrants, CIEL and its member company (Inquinoso) presently do not have any registered lindane end-use products. However, it is noted that lindane remains registered by other companies for use on a wide variety of food/feed crops such as fruit crops, field crops, and vegetable crops (including seed treatment) [Source: 5/29/01 search of EPA's REFS database]. CIEL and its member company have expressed intentions to support certain non-food uses and seed treatment uses of lindane on cereal grains (including barley, corn, oats, rye, sorghum, and wheat but excluding rice and wild rice).

The registrants have submitted PP#9F05057, for the establishment of time-limited tolerances for residues of lindane *per se* in/on the RACs of crops for which seed treatments are being proposed. Tolerances cannot be established or reassessed until an adequate plant metabolism study is submitted.

The registrants have also submitted PP#9F6022, for the establishment of tolerances on lindane *per se* in/on canola for which seed treatment is being proposed. Tolerances cannot be established or reassessed until an adequate plant metabolism study is submitted and additional residue data.

A tabular summary of the residue chemistry science assessments for reregistration of lindane is presented in Table A. When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the

generic data exemption) be amended such that they are consistent with the residue data which was submitted. A 30-day plantback interval for leafy vegetables and a 12-month plantback interval for all other unregistered crops is required on all of their end-use product labels for lindane.

GLN 860.1300: Nature of the Residue - Plants

The qualitative nature of lindane residues in plants reflecting seed treatment is inadequately understood. For the purpose of reregistration, the basic registrants are required to conduct a new plant metabolism study on lindane. This study should be conducted on a representative cereal grain, as the registrants have indicated that the only food uses they are supporting are for seed treatment of these crops. The new studies should be conducted at an application rate which will insure that sufficient ¹⁴C-residues are available for analysis. Crop samples should be harvested at the appropriate stage. In addition, care should be taken to insure that radioactivity is not lost during analysis. Identification of ¹⁴C-residues should also be confirmed using more than one method, or by GC/MS.

The results of the requested plant metabolism study will be considered by HED's MARC for determination of terminal residues of concern in cereal grains. Although the nature of the residue in plants remains inadequately understood at this time, HED has no objection to proceeding with the Lindane RED and with risk assessments, given that acceptable enforcement and data-collection methods are available for determining residues of lindane *per se* in/on plants and the proposed food/feed uses of lindane are limited to seed treatment. The HED MARC (T. Morton, 8/30/00, D267069) concluded that the total radioactive residues should be used for risk assessment purposes until adequate plant metabolism studies are submitted.

Plant metabolism studies reflecting postemergence foliar application on apples (MRID 40410902), cucumbers (MRID 40431204), and spinach (MRID 40431201) were previously submitted by the basic registrants in response to the requirements of the 9/85 Lindane Reregistration Guidance Document. These studies were deemed unacceptable and non-upgradable because of several deficiencies including inadequate characterization and identification of ¹⁴C-residues.

GLN 860.1300: Nature of the Residue - Animals

The qualitative nature of the residue in ruminants is adequately understood. The basic registrants had submitted a ruminant metabolism study (MRID 44867104) which was deemed inadequate but upgradable. To upgrade the study, the registrant was required to identify the metabolite labeled LiV in goat liver's aqueous phase which accounted for 25.2 % of the total radioactivity (0.57 ppm). In addition, storage stability data was required showing individual tissue sampling dates and final analysis dates. The registrant has recently submitted the required data (MRID 45224101, 45224102, and 45277201) thus, adequately addressing this deficiency. A brief summary of the recently reviewed goat metabolism study follows. Lactating goats were orally administered with [¹⁴C]lindane capsules immediately after morning milking once per day for seven days at a level equivalent to 13 ppm. Milk was collected twice daily and within 24 hours of the last dose, the animals were sacrificed. The total

radioactive residues (TRR; expressed as lindane equivalents) in collected samples were 3.46 ppm in fat, 2.25 ppm in liver, 0.48 ppm in kidney, 0.20 ppm in muscle, and 0.20 ppm in milk. The parent, lindane was the major residue identified in all goat matrices and accounted for approximately 56% of the TRR in milk fat, 85% of the TRR in fat, 81% of the TRR in muscle, 36% of the TRR in kidney, and 16% of the TRR in liver. Other metabolites present were: gamma-pentachlorocyclohexene (PCCH); 1,2,4-trichlorobenzene; gamma-tetrachlorocyclohexene (TCCH); 1,2-dichlorobenzene, a glutathione conjugate of a dichlorophenol, and a conjugate of a monochlorophenol.

The qualitative nature of the residue in poultry is adequately understood. A poultry metabolism study (MRIDs 40271301 and 44405404), submitted by the registrants in response to the 9/85 Lindane Reregistration Guidance Document, has recently been upgraded to acceptable status. A brief summary of the poultry metabolism study follows. Laying hens were dosed with [¹⁴C]lindane at levels equivalent to 1.2 ppm or 120 ppm in the diet for four consecutive days. Radioactive residues accumulated to the greatest extent in fatty tissues. In high dose hens, TRR levels were highest in fat (96.98 ppm) and lowest in breast muscle (1.44 ppm). TRR levels were proportionally less in tissues of low-dose hens (fat, 1.26 ppm; breast muscle 0.02 ppm). In eggs of high-dose hens, ¹⁴C-residues peaked on Day 4 at 10.83 ppm in yolks and 0.21 ppm in whites. Lindane was the major residue component identified and accounted for approximately 95% of the TRR in egg yolks, 71-86% of the TRR in muscle, skin, and fat, and 52% of the TRR in liver. Other metabolites that were identified included: 1,2,4-trichlorobenzene; 1,3,5-trichlorobenzene and dichlorobenzene(s); tetrachlorobenzene (either 1,2,4,5- or 1,2,3,4-); PCCH; 1,2,3,4-tetrachlorobenzene/tetrachlorocyclohexene; 1,2,3,4,5-pentachlorobenzene; and hexachlorocyclohexene.

The results of the ruminant and poultry metabolism studies will be presented to HED's MARC for determination of terminal residue of concern in eggs, milk, and animal tissues when an acceptable plant metabolism study is submitted. If the Committee determines that lindane *per se* is the only residue of concern requiring regulation, then the existing storage stability data for poultry commodities, the analytical method used for data collection, and the poultry feeding study will be upgraded to acceptable status.

The HED MARC (T. Morton, 8/30/00, D267069) concluded that the total radioactive residues should be used for risk assessment purposes until an adequate plant metabolism study is submitted.

GLN 860.1340: Residue Analytical Methods

Because the nature of the residue in plants resulting from seed treatment uses have not been adequately delineated, the adequacy of the available analytical methods cannot be determined. The registrants are reminded that radiovalidation of enforcement method(s) is a reregistration requirement; therefore, representative samples from the requested plant metabolism study should be used for radiovalidation and analyzed by the existing or proposed enforcement method(s) to determine whether total toxic residues are extracted from weathered samples.

Adequate methods are available for determination of residues of lindane *per se* in/on plant and animal commodities. The Pesticide Analytical Manual (PAM) Vol. II lists Methods I and II for the analysis of mixed isomers of 1,2,3,4,5,6-hexachlorocyclohexane in/on plant and animal commodities. Method I is a multiresidue method (see “GLN 860.1360: Multiresidue Methods” section) for chlorinated compounds. Method II is based upon the official final AOAC method (1990, 15th edition of AOAC) and is suitable for determining residues of lindane in/on AOAC Group I nonfatty foods (vegetables and fruits), dairy products, fish, and eggs. The stated limit of detection of Method II is 0.05 ppm for most commodities.

Adequate data-collection methods have been submitted for detection of lindane *per se* in/on cucumbers and spinach. The analytical procedures for detecting lindane in cucumbers and spinach are essentially the same. Residues of lindane are extracted with acetonitrile, partitioned with hexane:acetonitrile, cleaned up using Florisil column chromatography, and analyzed by gas chromatography with electron capture detection (ECD); the reported detection limit was 0.01 ppm. Based on acceptable method validation recoveries, the Agency has deemed the GC/ECD method to be adequate for determining residues of lindane *per se* in nonfatty crops.

A GC/MS method (SOP# Meth-109) entitled “Determination of Lindane in Wheat and Canola Matrices” was utilized as the data-collection method in a recently submitted wheat field study. Briefly, residues in/on wheat forage, hay, grain, and straw samples were extracted with acetonitrile and water. The water was salted out, and an aliquot of the remaining acetonitrile extract was purified by means of a hexane solvent partition, gel permeation chromatography, dichloromethane/salt water solvent partition, and a carbon black solid phase extraction cartridge cleanup. Detection and quantitation were conducted using a gas chromatograph equipped with a mass selective detector (GC/MS). The LOQ was 0.005 ppm.

A data-collection method, based on the AOAC method, was also submitted for detection of lindane *per se* in eggs, milk, and animal tissues. The Agency previously required an EPA method validation for the submitted method if lindane tolerances for lean animal tissues were to be established because the AOAC method did not describe techniques which the registrant’s method contained (e.g., gel permeation chromatography and rotary evaporation). The FDA method now utilizes these techniques; therefore, the requirement for a petition method validation was conditionally waived provided HED’s MARC determines that lindane *per se* is the only residue of concern in animal commodities.

GLN 860.1360: Multiresidue Methods

The 10/99 PESTDATA database (PAM, Vol. I, Appendix I) contains data concerning the applicability of multiresidue methods to lindane. Lindane is completely recovered (>80% recovery) using protocols 302 (Luke method), 303 (Mills, Onley, and Gaither method), and 304 (Mills method) for fatty and non-fatty foods. Should the HED MARC determine that lindane metabolites other than the parent should be regulated, the Agency will require the registrants to submit additional multiresidue methods test data for the metabolites of concern.

GLN 860.1380: Storage Stability Data

The specifics of reregistration requirements for storage stability data in plants and animals cannot be ascertained until acceptable plant metabolism studies are available, and the HED MARC has determined the terminal residues of concern. Assuming that lindane *per se* is the terminal residue of concern and provided the additional temperature information is submitted, the available storage stability data for lindane support the storage conditions and intervals of samples collected from existing crop field trials and livestock feeding studies. A summary of available storage stability data for lindane *per se* is summarized below.

Raw agricultural and processed commodities: Residues of lindane *per se* are relatively stable under frozen (-20^B C) storage conditions for up to 8 months in/on cucumbers and spinach and for approximately 14 months in/on tomatoes and wheat forage. Lindane residues are stable in wheat grain, wheat hay, and wheat straw for up to approximately 18 months when stored under frozen conditions. Lindane residues in canola seed were stable for up to 6.5 months when stored under frozen conditions (no temperature given). Lindane residues were stable for up to 2 months in canola oil and 1.5 months in canola meal when stored under frozen conditions (no temperature given). The registrant is required to submit additional storage stability data (temperature logs) specifying the storage conditions of the canola storage stability samples. Assuming that lindane *per se* is the terminal residue of concern, these data support the storage conditions and intervals of samples collected from existing crop field trials.

Animal commodities: Residues of lindane *per se* are relatively stable in eggs, milk, and edible tissues of animals stored frozen (-18^B C) for up to 9 months. Assuming that lindane *per se* is the terminal residue of concern, these data support the storage conditions and intervals of samples collected from existing ruminant and poultry feeding studies.

GLN 860.1500: Crop Field Trials

A translocation study (MRID 40431207) formed the basis for food-use classification of lindane when the pesticide is applied as a seed treatment. In this study, [¹⁴C]lindane was applied as a seed treatment to corn (field and sweet), mustard, radish, spinach, sugar beet, and wheat at approximately 1x the label rate. The treated seeds were then planted outdoors in 55 gallon drum halves and allowed to grow under simulated normal agricultural practices. Samples of immature and mature crop commodities were analyzed for total ¹⁴C, and some fractions were extracted with hexane and analyzed by a GC method for total lindane. The above study failed to adequately identify radioactive residues in/on all commodities grown from treated seed. Nonetheless, with the possible exception of wheat grain and foliage, residues were characterized to be not associated with biological molecules (e.g., amino acid, sugar, etc.) that have incorporated the radiolabel. The total residues found, the hexane-extractable residues, and the residues attributable to lindane are summarized in the table below. Should the HED MARC determine that lindane metabolites other than the parent should be regulated, the Agency will require the registrants to submit additional crop field trial data for all residues of concern.

Table 1. Residues in Various Crops Grown from Seed Treated with Lindane.

Crop Matrix	TRR (ppm)	Radioactivity in Hexane Extract	Residues Attributed to Lindane
Radish Root	0.056	0.038 ppm; 68% TRR	0.030 ppm; 54% TRR
Mustard Foliage	0.021	0.012 ppm; 57% TRR	0.017 ppm; 81% TRR ¹
Field Corn Root	0.340	0.307 ppm; 90% TRR	0.165 ppm; 49% TRR
Field Corn Foliage	0.064	0.016 ppm; 25% TRR	0.008 ppm; 13% TRR
Field Corn Grain	<0.01	--	--
Sweet Corn Foliage	0.051	0.060 ppm; 118% TRR	0.012 ppm; 24% TRR
Sweet Corn Grain	<0.01	--	--
Sugar Beet Root (Immature)	0.297	0.175 ppm; 59% TRR	0.090 ppm; 30% TRR
Sugar Beet Foliage	0.181	0.174 ppm; 96% TRR	0.035 ppm; 19% TRR
Wheat Foliage	2.925	0.136 ppm; 4.6% TRR	0.016 ppm; 0.55% TRR
Wheat Grain	0.052	--	0.002 ppm; 3.8% TRR
Spinach Leaves	0.020	--	--
¹ Lindane exceeds the TRR of extract.			

The registrants have submitted PP#9F05057, for the establishment of time-limited tolerances for residues of lindane *per se* in/on the RACs of crops for which seed treatments are being proposed. Tolerances cannot be established or reassessed until adequate plant metabolism studies are submitted.

The registrants have also submitted PP#9F6022, for the establishment of tolerances on lindane *per se* in/on canola for which seed treatment is being proposed. Tolerances cannot be established or reassessed until adequate plant metabolism studies are submitted.

In addition, the registrants recently submitted acceptable residue data reflecting seed treatment on wheat RACs. A representative formulation (Lindane 30-C) was applied as a seed treatment to wheat at 0.52 oz. ai/cwt (or 330 ppm lindane on the seed). Following treatment, the treated seeds were planted in 15 diverse geographic locations. Wheat forage samples were collected at or near the jointing stage, the hay samples at early flower to soft dough stage, and the grain and straw samples at normal harvest maturity. Residues of lindane were nondetectable (<0.005 ppm) in/on all treated wheat grain and straw samples. Residues of lindane ranged from <0.005 ppm (nondetectable) to 0.04 ppm in/on treated wheat forage and from <0.005 ppm (nondetectable) to 0.02 ppm in/on treated wheat hay. Additional residue data would be required if the HED MARC determines residues of concern include metabolites of lindane in addition to lindane *per se*.

GLN 860.1520: Processed Food/Feed

No data are available to determine whether lindane residues of concern concentrate in the processed fractions of corn following seed treatment. A processing study on corn is required for the purpose of reregistration. A processing study on wheat would also be required if the HED MARC determines residues of concern include metabolites of lindane in addition to lindane *per se*.

A processing study for wheat processed fractions is not being required if lindane *per se* is the only residue of concern (S. Funk, 10/31/95, D213401). In 1998, the U.S. Food and Drug Administration (FDA) monitoring program analyzed a total of 227 samples of milled grain products for lindane residues at an LOQ of 0.01 ppm. Commodities analyzed included flour and other milled products, breakfast foods, and baked goods. Lindane was not detected in any sample.

The registrant submitted a canola processing study along with PP#9F6022 where lindane residues in/on canola refined oil, canola meal, and bleached/deodorized canola oil were determined. Lindane in canola refined oil concentrated by a factor of at least 5.2x. Lindane did not concentrate in canola meal and bleached/deodorized canola oil.

GLN 860.1480: Meat, Milk, Poultry, Eggs

The nature of the residue in plants is not understood. Upon receipt of the requested plant metabolism data, the Agency will: (I) determine the adequacy of established tolerances for animal commodities; (ii) calculate the expected dietary intake for beef cattle, dairy cattle, and swine; and (iii) re-evaluate the need for additional feeding studies.

It should be noted that ruminant (M. Kovacs, 9/20/88, CB No. 4037) and poultry feeding (G. Otakie, 8/31/88, RCB No. 4034) studies are available (summarized below) assuming that lindane *per se* is the only residue of concern in animals.

Ruminant Feeding Study

Thirteen lactating Holstein cows were orally administered gelatin capsules containing lindane daily for 28 consecutive days. The cows were assigned to four groups (four cows per dose group plus one control). Three of the four cows in each dosing level were also dermally treated via a dip tank on day 21 and 28. Lindane residues in Table 2 are from the single cow which did not receive the dip treatment. Cows were housed in a common area. The administered dose levels were 20 ppm, 60 ppm, and 200 ppm which are equivalent to 143x, 426x, and 1,418x the maximum lindane dietary burden of 0.141 ppm for dairy cattle (assuming lindane is the sole residue of concern). **Using the total radioactive residues for feed items as required by the HED MARC, the feeding levels are equivalent to 3x, 10x, and 34x the maximum lindane dietary burden for dairy cattle (equivalent to 7x, 20x, and 67x the maximum lindane dietary burden for beef cattle).** The calculation of expected dietary intake for beef and dairy cattle, using feed items derived from proposed seed treatment uses, is presented in Table 2. The daily dose was given to each cow after the morning

milking. Milk subsamples were collected for analysis on days 0, 1, 3, 7, 14, 21, 25, and 28. Tissue samples were collected from each cow after sacrifice by exsanguination.

All tissue samples were immediately frozen on dry ice and stored at -15[°]C for 4 to 4½ months prior to residue analysis. Milk samples were stored at -15[°]C for 1 to 3 months prior to analysis. The available storage stability data indicate that lindane *per se* is relatively stable in eggs, milk, and edible tissues of animals stored frozen (-18[°]C) for up to 9 months. These data support the storage conditions and intervals of samples collected from dairy cattle feeding study. Samples were analyzed for lindane residues by validated AOAC Multiresidue GLC methodology with electron capture detection.

Table 2. Calculation of maximum dietary burdens of beef cattle, dairy cattle, and swine for lindane using feed items derived from seed treatment.

Feed Commodity	% Dry Matter	% Diet	Reassessed Tolerance (ppm) ²	Dietary Contribution (ppm) ¹
Beef Cattle				
Corn forage	40	40	0.1	0.100
Corn grain	88	60	0.01	0.007
Total Burden				0.107
Dairy Cattle				
Corn forage	40	50	0.1	0.125
Corn grain	88	40	0.01	0.004
Corn stover	83	10	0.1	0.012
Total Burden				0.141
Swine				
Corn grain	NA	80	0.01	0.008
Wheat grain	NA	20	0.005	0.001
Total Burden				0.009

¹ Contribution = [reassessed tolerance / % DM] X % diet).

² Reassessed tolerance if lindane *per se* is determined by the HED MARC to be the only residue of concern.

The results of the dairy cattle feeding study are presented in Table 3. There appears to be a linear correlation between the dose level and the residue found for each tissue and for milk. Residues of lindane in milk plateaued on Day-7. By extrapolation of residue levels obtained at the 20-ppm dosing levels, the maximum expected residues of lindane in dairy cattle milk and tissues are all below 0.01 ppm except in the fat where the predicted maximum residue is 0.084 ppm.

Table 3. Residues of lindane in milk and meat of dairy cattle dosed with lindane in the diet at 20, 60 and 200 ppm for 28 consecutive days.

Tissue	Lindane Residues (ppm) Obtained at Various Dosing Levels		
	20 ppm	60 ppm	200 ppm
Liver	0.10	0.19	0.72
Kidney	0.34	1.07	4.57
Heart	1.23	1.56	10.3
Muscle	0.97	1.80	8.75
Fat	11.9	20.2	158.1
Milk Day-7	0.47	1.08	5.20
Day-14	0.17	0.75	3.12
Day-21	0.19	1.02	7.08
Day-25	0.31	1.19	5.49
Day-28	0.67	1.90	10.81

Poultry Feeding Study

Sixty White Leghorn laying hens were orally administered gelatin capsules containing lindane daily for 28 consecutive days. The hens were assigned to fourteen groups (four hens per group, 4 groups per dose level plus two control groups). The administered dose levels were 1.5 ppm, 4.5 ppm, and 15 ppm which are equivalent to 15x, 45x, and 150x the maximum lindane dietary burden of 0.10 ppm for poultry as calculated by the registrant. The daily dose was given to each hen at the daily egg sampling and feeding. Egg samples were collected for analysis on days 0, 1, 3, 7, 14, 21, 25, and 28. Tissue samples were collected from each hen after sacrifice by exsanguination. Tissue samples were composited by group (four hens).

All tissue samples were immediately frozen on dry ice and stored at -15^B C for a maximum of 5 months prior to residue analysis. Egg samples were stored at -15^B C for a maximum of 5 months prior to analysis. The available storage stability data indicate that lindane *per se* is relatively stable in eggs, milk, and edible tissues of animals stored frozen (-18^B C) for up to 9 months. These data support the storage conditions and intervals of samples collected from the poultry feeding study. Samples were analyzed for lindane residues by validated AOAC Multiresidue GLC methodology with electron capture detection.

The results of the poultry feeding study are presented in Table 4. There appears to be a linear correlation between the dose level and the residue found for eggs and each tissue. Residues of lindane in eggs plateaued by Day-14. By extrapolation of residue levels obtained at the 1.5-ppm dosing levels, the maximum expected residues of lindane in poultry eggs and tissues are all below 0.01 ppm except in the kidney, fat, and eggs where the predicted maximum residues are 0.011, 0.169, and 0.014 ppm, respectively.

Table 4. Residues of lindane in eggs and tissues of laying hens dosed with lindane in the diet at 1.5, 4.5 and 15 ppm for 28 consecutive days.

Tissue	Lindane Residues (ppm) Obtained at Various Dosing Levels		
	1.5 ppm	4.5 ppm	15 ppm
Liver	0.12	0.51	0.78
Kidney	0.17	0.55	2.03
Heart	0.33	0.89	2.26
Gizzard	0.10	0.32	0.95
Thigh	0.19	0.36	1.35
Breast	0.03	0.10	0.37
Fat	2.54	7.75	27.65
Eggs Day-7	0.110	0.258	0.878
Day-14	0.216	0.609	2.14
Day-21	0.185	0.603	2.36
Day-25	0.189	0.672	2.10
Day-28	0.205	0.588	2.38

GLN 860.1400: Water, Fish, and Irrigated Crops

Lindane is presently not registered for direct use on water and aquatic food and feed crops; therefore, no residue chemistry data are required under this guideline topic.

GLN 860.1460: Food Handling

Lindane is presently not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

The basic registrants have submitted a confined rotational crop study which was deemed unacceptable and not upgradable because of inadequate characterization and identification of residues due to significant losses of organosoluble residues during analysis. Although the study is inadequate and the application rate used (0.75 lb ai/A) greatly exceeds the level of soil residues that are likely to result from seed-treatment uses, the data indicate that residues of lindane persist in the soil and can be taken up by rotational crops at intervals up to one year.

For the purpose of reregistration, the Agency will not require a new confined rotational crop study provided the registrants propose a 30-day plantback interval for leafy vegetables and a 12-month plantback interval for all other unregistered crops on all of their end-use product labels for lindane. If this recommendation is not acceptable to the registrants, then limited rotational field trial data are required. The limited field trials should be conducted on a representative crop (as defined in 40 CFR 180.41) at two sites per crop for the following three crop groups: root and tuber vegetables, leafy

vegetables and small grains (wheat, barley, oats, and rye) for a total of six trials. As with confined studies (OPPTS 860.1850), soybeans may be substituted for the leafy vegetable. The six trials should be conducted on crops which a registrant intends to have as rotational crops on the label. In addition, some of the six trials could be conducted using other crops that are typically involved in crop rotation such as alfalfa and soybeans. The registrants have informed the Agency they will propose the specified plantback intervals.

The results of the confined rotational crop study are summarized in the tables below.

Table 5a. Summary of the characterization/identification of radioactive residues in/on **barley forage** grown in sandy loam soil treated with [¹⁴C]lindane at 0.75 lb ai/A (22x the seed treated barley application rate).

Metabolite	30-DAT Barley Forage (TRR = 0.0991 ppm)		121-DAT Barley Forage (TRR = 0.3939 ppm)		365-DAT Barley Forage (TRR = 0.1082 ppm)	
	%TRR	ppm	%TRR	ppm	%TRR	ppm
Identified						
Lindane	15.79	0.0156	26.18	0.1031	3.17	0.0034
2,4-Dichlorophenol	2.43	0.0024	1.02	0.0040	--	--
2,4,5-Trichlorophenol	2.96	0.0029	2.89	0.0114	--	--
2,3,4,6-Tetrachlorophenol	--	--	4.45	0.0175	--	--
Total identified	21.18	0.0209	34.54	0.1360	3.17	0.0034
Characterized						
Unidentified Residues	3.65	0.0036	0.05	0.0002	9.31	0.0101
Total identified/ characterized	24.83	0.0245	34.59	0.1362	12.48	0.0135
Nonextractable	51.36	0.0509	39.30	0.1548	40.39	0.0437

Table 5b. Summary of the characterization/identification of radioactive residues in/on **barley straw and grain** grown in sandy loam soil treated with [¹⁴C]lindane at 0.75 lb ai/A.

Metabolite	30-DAT Barley Straw (TRR = 0.3866 ppm)		121-DAT Barley Straw (TRR = 0.9341 ppm)		30-DAT Barley Grain (TRR = 0.0478 ppm)	
	%TRR	ppm	%TRR	ppm	%TRR	ppm
Identified						
Lindane	0.36	0.0014	2.42	0.0226	--	--
4-Chlorophenol	16.61	0.0642	0.90	0.0084	8.79	0.0042
2,4-Dichlorophenol	3.80	0.0147	2.28	0.0213	2.09	0.0010
2,4,5-Trichlorophenol	1.82	0.0070	1.06	0.0099	3.35	0.0016
Total identified	22.59	0.0873	6.66	0.0622	14.23	0.0068
Characterized						
Unidentified Residues	2.58	0.0100	1.73	0.0161	--	--
Acid hydrolysate	--	--	7.37	0.0688	--	--
Total identified/ characterized	25.17	0.0973	15.76	0.1471	14.23	0.0068

Nonextractable	NR	NR	78.21	0.7306	NR	NR
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NR = not reported

Table 6a. Summary of the characterization/identification of radioactive residues in/on **mature carrot root** grown in sandy loam soil treated with [¹⁴C]lindane at 0.75 lb ai/A.

Metabolite	30-DAT Mature Carrot Root (TRR = 0.4447 ppm)		121-DAT Mature Carrot Root (TRR = 0.4081 ppm)		365-DAT Mature Carrot Root (TRR = 0.3984 ppm)	
	% TRR	ppm	% TRR	ppm	% TRR	ppm
Identified						
Lindane	47.65	0.2119	83.12	0.3392	88.78	0.3537
Pentachlorocyclohexene	--	--	5.61	0.0229	3.21	0.0128
Total identified	47.65	0.2119	88.73	0.3621	91.99	0.3665
Characterized						
Unidentified Residues	2.41	0.0107	3.16	0.0129	2.81	0.0112
Total identified/ characterized	50.06	0.2226	91.89	0.3750	94.80	0.3777
Nonextractable	1.03	0.0046	2.50	0.0102	0.90	0.0036

Table 6b. Summary of the characterization/identification of radioactive residues in/on **mature carrot tops** grown in sandy loam soil treated with [¹⁴C]lindane at 0.75 lb ai/A.

Metabolite	30-DAT Mature Carrot Tops (TRR = 0.0916 ppm)		121-DAT Mature Carrot Tops (TRR = 0.1857 ppm)		365-DAT Mature Carrot Tops (TRR = 0.0637 ppm)	
	% TRR	ppm	% TRR	ppm	% TRR	ppm
Identified						
Lindane	69.19	0.0634	91.12	0.1692	18.45	0.0118
Total identified	69.19	0.0634	91.12	0.1692	18.45	0.0118
Characterized						
Unidentified Residues	14.44	0.0132	2.80	0.0052	37.28	0.0237
Total identified/ characterized	83.63	0.0766	93.92	0.1744	55.73	0.0355
Nonextractable	13.21	0.0121	10.29	0.0191	29.04	0.0409

Table 7. Summary of the characterization/identification of radioactive residues in/on **immature and mature lettuce** grown in sandy loam soil treated with [¹⁴C]lindane at 0.75 lb ai/A. ^a

Metabolite	30-DAT Immature Lettuce (TRR = 0.0207 ppm)		121-DAT Immature Lettuce (TRR = 0.0419 ppm)		30-DAT Mature Lettuce (TRR = 0.0429 ppm)	
	%TRR	ppm	%TRR	ppm	%TRR	ppm
Identified						
Lindane	137.57	0.0285	26.08	0.0109	42.80	0.0184
4-Chlorophenol	--	--	--	--	7.56	0.0032
2,4,5-Trichlorophenol	--	--	--	--	7.02	0.0030
2,3,4,6-Tetrachlorophenol	--	--	--	--	4.30	0.0018
Total identified	137.57	0.0285	26.08	0.0109	61.68	0.0264
Characterized						
Unidentified Residues	--	--	5.66	0.0024	5.45	0.0023
Total identified/ characterized	137.57	0.0285	31.74	0.0133	67.13	0.0287
Nonextractable	32.37	0.0067	24.58	0.0103	35.20	0.0151

^a Organosoluble ¹⁴C-residues were #0.01 ppm from 365-day immature lettuce and 121- and 365-day mature lettuce samples and were not further characterized.

Table A. Residue Chemistry Science Assessments for Reregistration of Lindane.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR §180.133]	Must Additional Data Be Submitted?	References ¹
860.1200: Directions for Use	N/A = Not Applicable	Yes ²	REFS search of 5/29/01
860.1300: Plant Metabolism	N/A	Yes ³	00025707, 00060143, 00060150, 00105413, GS-00010, GS-00012, GS-00013, GS-00019, 40410902 ⁴ , 40431201 ⁴ , 40431204 ⁴ , 44383001 ⁵ , 44383002 ⁵ , 44405403 ⁶
860.1300: Animal Metabolism	N/A	No ⁷	GS-00014, GS-00015, GS-00016, 40271301 ⁸ , 40271302 ⁹ , 44405404 ⁶ , 44867104 ¹⁰ , 45224101 ¹¹ , 45224102 ¹¹ , 45277201 ¹¹
860.1340: Residue Analytical Methods			
- Plant commodities	N/A	Reserved ¹²	05006312, GS-00018, 40431202 ¹³ , 40431206 ¹³ , 44383003 ⁵ , 44383004 ⁵ , 44909901 ¹⁴
- Animal commodities	N/A	Reserved ¹²	00025690, 00032233, 00099909, 05002348, 05003005, GS-00017, 40431208 ¹⁵ , 44440601 ¹⁶ , 44867105 ¹⁰
860.1360: Multiresidue Methods	N/A	Reserved ¹⁷	
860.1380: Storage Stability Data			
- Plant commodities	N/A	Yes ¹⁸	40431203 ¹⁹ , 40431205 ¹⁹ , 41699701 ²⁰ , 44440602 ¹⁶ , 44909901 ¹⁴
- Animal commodities	N/A	Reserved ²¹	40660502 ²² , 44440603 ¹⁶ , 44867106 ¹⁰

Table A (*continued*).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR §180.133]	Must Additional Data Be Submitted?	References ¹
860.1500: Crop Field Trials			
[NOTE: The basic registrants are supporting only seed treatment uses of lindane on cereal grains (including barley, corn, oats, rye, sorghum, and wheat but excluding rice and wild rice). The rows corresponding to these crops are shaded.]			
<u>Root and Tuber Vegetables Group</u>			
- Beet, sugar, root	None established	No ²³	40431207 ²⁴
- Radish, root	None established	No ²⁵	40431207 ²⁴
<u>Leaves of Root and Tuber Vegetables Group</u>			
- Beet, sugar, tops (leaves)	None established	No ²³	40431207 ²⁴
- Radish, tops (leaves)	None established	No ²⁵	40431207 ²⁴
<u>Bulb Vegetables (<i>Allium</i> spp.) Group</u>			
- Onions (dry bulb)	1	No ²³	
<u>Leafy Vegetables (Except <i>Brassica</i> Vegetables) Group</u>			
- Celery (seed treatment)	1	No ²³	
- Lettuce (seed treatment)	3	No ²⁶	41289407
- Spinach (seed treatment)	1	No ²⁶	40431207 ²⁴
- Swiss chard (seed treatment)	1	No ²³	
<u><i>Brassica</i> (Cole) Leafy Vegetables Group</u>			
- Broccoli (seed treatment)	1	No ²⁷	
- Brussels sprouts (seed treatment)	1	No ²⁷	
- Cabbage (seed treatment)	1	No ²⁷	41289403
- Cauliflower (seed treatment)	1	No ²⁷	

Table A (*continued*).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR §180.133]	Must Additional Data Be Submitted?	References ¹
- Collards (seed treatment)	1	No ²³	
- Kale (seed treatment)	1	No ²³	
- Kohlrabi (seed treatment)	1	No ²³	
- Mustard greens (seed treatment)	1	No ²³	40431207 ²⁴
- Rape greens (seed treatment)	None established	No ²³	
<u>Fruiting Vegetables (Except Cucurbits) Group</u>			
- Eggplant	1	No ²³	
- Pepper	1	No ²³	
- Tomato	3	No ²³	41699701 ²⁰ , 41861201 ²⁸
<u>Cucurbit Vegetables Group</u>			
- Cucumber	3	No ²³	41289404
- Melons	3	No ²³	
- Pumpkin	3	No ²³	
- Squash	3	No ²³	
<u>Pome Fruits Group</u>			
- Apple	1	No ²³	41289401
- Pear	1	No ²³	
- Quince	1	No ²³	
<u>Stone Fruits Group</u>			
- Apricot	1	No ²³	

Table A (*continued*).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR §180.133]	Must Additional Data Be Submitted?	References ¹
- Cherry	1	No ²³	
- Nectarine	1	No ²³	
- Peach	1	No ²³	41289408
- Plum (fresh prune)	1	No ²³	
<u>Tree Nuts Group</u>			
- Pecan	0.01	No ²³	41289601, 41421001
<u>Cereal Grains Group</u>			
- Barley grain (seed treatment)	None established	No ²⁹	
- Corn grain (seed treatment)	None established	No	40431207 ²⁴
- Oats grain (seed treatment)	None established	No ²⁹	
- Rye grain (seed treatment)	None established	No ²⁹	
- Sorghum grain (seed treatment)	None established	No ³²	40431207 ²⁴
- Wheat grain (seed treatment)	None established	No ²⁹	40431207 ²⁴ , 44909901 ¹⁴
- Canola grain (seed treatment)	None established	Yes ³⁰	44864401 ³¹ , 45310501 ³¹
<u>Forage, Fodder, and Straw of Cereal Grains Group (Excluding Rice and Wild Rice)</u>			
- Barley hay and straw (seed treatment)	None established	No ²⁹	
- Corn forage and stover (seed treatment)	None established	No	40431207 ²⁴
- Oats forage, hay, and straw (seed treatment)	None established	No ²⁹	
- Rye forage and straw (seed treatment)	None established	No ²⁹	

Table A (*continued*).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR §180.133]	Must Additional Data Be Submitted?	References ¹
- Sorghum forage and stover (seed treatment)	None established	No ³²	40431207 ²⁴
- Wheat forage, hay, and straw (seed treatment)	None established	No ²⁹	40431207 ²⁴ , 44909901 ¹⁴
- Canola forage, hay, and straw (seed treatment)	None established	Yes ³⁰	44864401 ³¹ , 45310501 ³¹
<u>Miscellaneous Commodities</u>			
- Asparagus	1	No ²³	
- Avocado	1	No ²³	
- Grape	1	No ²³	41289405
- Guava	1	No ²³	
- Mango	1	No ²³	
- Miscellaneous crops with seed treatments only	None established	No ²³	40431207 ²⁴
- Mushroom	3	No ²³	
- Okra	1	No ²³	
- Pineapple	1	No ²³	
- Strawberry	1	No ²³	
- Tobacco	None established	No ²³	41289409
860.1520: Processed Food/Feed			
- Apple	None established	No ²³	41289402
- Canola	None established	Yes ¹⁸	44864401 ³¹ , 45310501 ³¹

Table A (*continued*).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR §180.133]	Must Additional Data Be Submitted?	References ¹
- Cereal grains	None established	Yes ³³	
- Grape	None established	No ²³	41289406
- Tomato	None established	No ²³	41861202 ²⁸
860.1480: Meat, Milk, Poultry, Eggs			
- Milk, Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	7 (fat of meat from cattle, goats, horses, and sheep); 4 (fat of meat from hogs)	Reserved ⁴⁰	00025685, 00045126, 00075989, 00088048, 00088165, 00089592, 00101478, 00104441, 00118722, 00118723, 00118724, 00118725, 00118739, GS-00018, GS-00021, GS-00022, GS-00023, 40660503³⁴, 40660504³⁵, 40660505³⁶
- Eggs and the Fat, Meat, and Meat Byproducts of Poultry	None established	Reserved ⁴⁰	40660501 ³⁷ , 44440604 ¹⁶
860.1400: Water, Fish, and Irrigated Crops	None established	No	
860.1460: Food Handling	None established	No	
860.1850: Confined Rotational Crops	N/A	No ³⁸	41967301 ³⁹
860.1900: Field Rotational Crops	None established	Reserved ³⁸	

- Bolded** references were reviewed in the Residue Chemistry Chapter to the Lindane Reregistration Standard dated 6/7/85 and its 9/5/85 addendum. *Italicized* references were reviewed in the Lindane Product and Residue Chemistry Reregistration Standard Updates (CB No. 6961, 1/31/91, E. Zager). All other references were reviewed as noted. The basic registrants are supporting only seed treatment uses of lindane on cereal grains (including barley, corn, oats, rye, sorghum, and wheat but excluding rice and wild rice). The rows corresponding to these crops are shaded.
- The registrants must submit a formal petition for the establishment of tolerances for all appropriate RACs being supported for seed treatment uses. The petition should include all requisite petition sections including a Section B specifying the maximum use rate (in terms of oz ai/100 lb of seeds or cwt) and information pertaining to recommended seeding rate per acre should be included in order to allow the Agency to calculate

Table A (*continued*).

- rates in terms of lb ai/A. In addition, the registrants should formally request the cancellation of all food/feed uses except seed treatment and requests that all labels for the agricultural use of formulated lindane be revised to allow only seed treatment uses.
3. A new plant metabolism study reflecting seed treatment are required. This study should be conducted on a representative cereal grain as the registrants have indicated that the only food/feed uses they are supporting are for seed treatment of these crops. Crop samples should be harvested at the appropriate stage. In addition, care should be taken to insure that radioactivity is not lost during analysis. Identification of ¹⁴C-residues should also be confirmed using more than one method, or by GC/MS.
 4. CB No. 3267, 3/24/88, G. Otakie.
 5. DP Barcode D239699, 12/16/97, S. Funk.
 6. DP Barcode D240495, 12/14/99, T. Morton.
 7. The qualitative nature of the residue in ruminants and poultry is adequately understood. The results of the ruminant and poultry metabolism studies will be presented to the HED Metabolism Assessment Review Committee (MARC) for determination of terminal residue of concern in eggs, milk, and animal tissues when an acceptable plant metabolism study is submitted. If the HED MARC determines that lindane is the only residue of concern requiring regulation, then the existing storage stability data for livestock commodities, the analytical method used for data collection, and the livestock feeding studies will be upgraded to acceptable status.
 8. CB No. 3315, 3/24/88, J. Onley.
 9. CB No. 3312, 3/24/88, C. Deyrup.
 10. DP Barcode D257805, 12/14/99, T. Morton.
 11. DP Barcode D271442 and D274158, 4/18/01, T. Morton.
 12. Adequate methods are available for determination of residues of lindane *per se* in/on plant and animal commodities. However, the adequacy of the available analytical methods cannot be determined until the registrants submit acceptable plant metabolism studies reflecting seed treatment, and the HED MARC has determined the total toxic residues of lindane that need to be included in the tolerance expression. The registrants are reminded that radiovalidation of enforcement method(s) is a reregistration requirement; representative samples from the requested plant metabolism study should be used for radiovalidation and analyzed by the existing or proposed enforcement method(s) to determine whether total toxic residues are extracted from weathered samples.
 13. CB No. 3257, 3/24/88, N. Dodd.
 14. DP Barcode D259318, 8/30/00, T. Morton.
 15. CB No. 3261, 3/24/88, N. Dodd.
 16. DP Barcode D242510, 12/14/99, T. Morton.
 17. Should the HED MARC determine that lindane metabolites other than the parent should be regulated, the Agency will require the registrants to submit additional multiresidue methods test data for the metabolites of

Table A (*continued*).

- concern.
18. Additional storage stability data (temperature logs) are required for the canola field trials and the canola processing study. Storage stability data are also required to support the requested corn processing study. Additional storage stability data may be required if the HED MARC determines that additional lindane metabolites of concern need to be included in the tolerance expression.
 19. CB No. 3260, 3/24/88, N. Dodd.
 20. CB No. 7470, 3/29/91, R. Perfetti.
 21. Assuming that lindane *per se* is the terminal residue of concern in animal commodities, adequate storage stability data are available to support the storage conditions and intervals of samples collected from existing ruminant and poultry feeding studies. Additional storage stability data may be required if the HED MARC determines that additional lindane metabolites of concern need to be included in the tolerance expression.
 22. CB No. 4035, 8/23/88 and 8/26/88 (addendum), S. Willett.
 23. Because no registrants have committed to support use(s) of lindane on this crop, no residue data are required. The Agency recommends that this use site be deleted from all lindane end-use products. The Agency also recommends the revocation of existing lindane tolerances, if established, on the RACs of crops which are not being supported.
 24. CB No. 3259, 3/24/88, N. Dodd.
 25. Because no registrants have committed to support use(s) of lindane on this crop, no residue data are required. The Agency recommends that this use site be deleted from all lindane end-use products. The Agency also recommends the revocation of existing lindane tolerances, if established, on the RACs of crops which are not being supported.
 26. Because no registrants have committed to support use(s) of lindane on this crop, no residue data are required. The Agency recommends that this use site be deleted from all lindane end-use products. The Agency also recommends the revocation of existing lindane tolerances, if established, on the RACs of crops which are not being supported.
 27. Because no registrants have committed to support use(s) of lindane on this crop, no residue data are required. The Agency recommends that this use site be deleted from all lindane end-use products. The Agency also recommends the revocation of existing lindane tolerances, if established, on the RACs of crops which are not being supported.
 28. CB No. 8075, DP Barcode D164898, 4/8/92, R. Perfetti.
 29. Assuming that lindane *per se* is the terminal residue of concern in plants, the available residue data, reflecting seed treatment, for wheat grain, forage, hay, and straw may be translated to the RACs of barley, oats, and rye, provided the registrants propose identical use patterns and tolerances. The registrants may propose a maximum seed treatment rate of 0.052 oz ai/cwt (or 330 ppm lindane on the seed) on small cereal grains which is supported by adequate residue data.
 30. Assuming that lindane *per se* is the terminal residue of concern in plants, two additional field trials are required for canola.

Table A (*continued*).

31. DP Barcode 269388 and D273830, 5/10/01, T. Morton.
32. Assuming that lindane *per se* is the terminal residue of concern in plants, the available seed treatment data for corn may be translated to sorghum, provided the registrants propose identical use patterns and tolerances.
33. The registrants are required to submit processing data to determine whether lindane residues of concern concentrate in the processed fractions of corn following seed treatment.
34. CB No. 4036, 8/31/88, M. Kovacs.
35. CB No. 4038, 8/29/88, S. Willett.
36. CB No. 4037, 9/20/88, M. Kovacs.
37. CB No. 4034, 8/31/88, G. Otakie.
38. For the purpose of reregistration, the Agency will not require a new confined rotational crop study provided the registrants propose a 30-day plantback interval for leafy vegetables and a 12-month plantback interval for all other unregistered crops on all of their end-use product labels for lindane. If this recommendation is not acceptable to the registrants, then limited rotational field trial data are required. The limited field trials should be conducted on a representative crop (as defined in 40 CFR 180.41) at two sites per crop for the following three crop groups: root and tuber vegetables, leafy vegetables and small grains (wheat, barley, oats, and rye) for a total of six trials. As with confined studies (OPPTS 860.1850), soybeans may be substituted for the leafy vegetable. The six trials should be conducted on crops which a registrant intends to have as rotational crops on the label. In addition, some of the six trials could be conducted using other crops that are typically involved in crop rotation such as alfalfa and soybeans. The registrant has informed the Agency they will propose the specified plantback intervals.
39. DP Barcodes D172626 and D198353, 8/30/00, T. Morton.
40. The nature of the residue in plants is not understood. Upon receipt of the requested plant metabolism data, the Agency will: (I) determine the adequacy of established tolerances for animal commodities; (ii) calculate the expected dietary intake for beef cattle, dairy cattle, and swine; and (iii) reevaluate the need for additional feeding studies. Assuming that lindane *per se* is the only residue of concern in animals, acceptable ruminant and poultry feeding studies are available.

TOLERANCE REASSESSMENT SUMMARY

Tolerances for residues of lindane in/on raw agricultural and animal commodities are established under 40 CFR §180.133 and expressed in terms of residues of lindane *per se* [gamma isomer of benzene hexachloride]. The residue definition for lindane is misleading and should be amended as follows to harmonize with IUPAC nomenclature: gamma isomer of 1,2,3,4,5,6-hexachlorocyclohexane. Plant commodity tolerances for lindane were originally established based on registered uses which included preplant soil application, foliar applications, and seed treatments. Animal commodity tolerances were established based on uses which included direct livestock animal treatment as well as animal premise treatment. Refer to Table B for a list of established lindane tolerances.

The only food/feed use of lindane which is being supported for reregistration is seed treatment on cereal grains (excluding rice and wild rice).

A definitive reassessment of the currently established tolerances for lindane cannot be made at this time due to major deficiencies in the residue chemistry database. The Agency tentatively concludes that no changes in the present tolerance expression are required at this time until the nature of the residue in plants and animals is adequately elucidated, and HED's MARC has determined the terminal residues of concern. Because of the Agency's concerns about the possibility of human health effects due to dietary exposure to lindane and the lack of data to support seed treatment uses, no additional tolerances other than those required to support the basic registrants' proposed seed treatment uses, will be considered until the data gaps identified in this Residue Chemistry Chapter are fulfilled.

The listing of lindane tolerances under 40 CFR §180.133 should be subdivided into parts (a), (b), (c), and (d). Part (a) should be reserved for commodities with permanent tolerances, part (b) for Section 18 emergency exemptions, part © for tolerances with regional registrations, and part (d) for indirect or inadvertent residues.

Tolerances Listed Under 40 CFR §180.133:

Following resolutions of residue chemistry data deficiencies specified in this Residue Chemistry Science Chapter, a statement in 40 CFR §180.133 should be added to specify that the established tolerances result from seed treatment only.

The established tolerances for the following commodities should be revoked because no registrants have committed to support their uses: apples, apricots, asparagus, avocados, broccoli, Brussels sprouts, cabbage, cauliflower, celery, cherry, collards, cucumbers, eggplants, grapes, guavas, kale, kohlrabi, lettuce, mangoes, melons, mushrooms, mustard greens, nectarines, okra, onions (dry bulb only), peaches, pears, pecans, peppers, pineapple, plums (fresh prunes), pumpkins, quinces, radish, spinach, squash, strawberries, summer squash, swiss chard, and tomatoes.

Tolerances To Be Proposed Under 40 CFR §180.133:

Tolerances for lindane residues of concern need to be established for: barley, grain; barley, hay; barley, straw; corn, grain; corn, forage; corn, stover; oat, grain; oat, forage; oat, hay; oat, straw; rye, grain; rye, forage; rye, straw; sorghum, grain; sorghum, forage; sorghum, stover; wheat, grain; wheat, forage; wheat, hay; and wheat, straw once required data are submitted. In addition, the need for tolerances for livestock tissues, milk, poultry tissues and eggs will be reevaluated once additional plant metabolism data is submitted.

Pending Tolerance Petitions:

In 1993, CIEL proposed to delete all food/feed uses except seed treatment. Concomitantly, CIEL proposed to establish tolerances of 0.1 ppm for residues of lindane *per se* in/on several RACs as a result of seed treatment. In an initial Agency review (DP Barcode D213401, 10/31/95, S. Funk) of available residue data reflecting seed treatment, the Agency concluded that the proposed tolerances were adequate in some instances and inadequate or non-acceptable in others. In those instances where the proposed tolerances were deemed inadequate, the reviewer proposed values that HED would consider as appropriate.

In 1998, CIEL submitted a petition, PP#9F05057, for the establishment of time-limited tolerances for residues of lindane *per se* in/on several commodities resulting from seed treatment. The Agency review (DP Barcodes D254236, 8/30/00, T. Morton) of these tolerance proposals concluded that tolerances could not be established until an adequate plant metabolism study was submitted.

The registrants have also submitted PP#9F6022, (D269388, T. Morton, 5/10/01) for the establishment of tolerances on lindane *per se* in/on canola for which seed treatment is being proposed. Tolerances cannot be established or reassessed until an adequate plant metabolism study is submitted.

Table B. Tolerance Reassessment Summary for Lindane.

Commodity	Tolerance Listed Under 40 CFR (ppm)	Reassessed Tolerance (ppm)	Comment [Correct Commodity Definition]
Tolerance Listed Under 40 CFR §180.133			
Apples	1	Revoke	Not being supported for reregistration.
Apricots	1	Revoke	Not being supported for reregistration.
Asparagus	1	Revoke	Not being supported for reregistration.
Avocados	1	Revoke	Not being supported for reregistration.
Broccoli	1	Revoke	Not being supported for reregistration.
Brussels sprouts	1	Revoke	Not being supported for reregistration.
Cabbage	1	Revoke	Not being supported for reregistration.
Cauliflower	1	Revoke	Not being supported for reregistration.
Lettuce	3	Revoke	Not being supported for reregistration.
Spinach	1	Revoke	Not being supported for reregistration.
Celery	1	Revoke	Not being supported for reregistration.
Collards	1	Revoke	Not being supported for reregistration.
Kale	1	Revoke	Not being supported for reregistration.
Kohlrabi	1	Revoke	Not being supported for reregistration.
Mustard greens	1	Revoke	Not being supported for reregistration.
Swiss chard	1	Revoke	Not being supported for reregistration.
Cherry	1	Revoke	Not being supported for reregistration.
Cucumbers	3	Revoke	Not being supported for reregistration.
Eggplants	1	Revoke	Not being supported for reregistration.
Fat of meat from cattle, goats, horses, and sheep	7	To be determined (TBD)	The Agency will re-calculate the maximum theoretical dietary burden for livestock animals and re-assess the adequacy of the available animal feeding studies when the requested residue data for livestock feed items have been received and evaluated.
Fat of meat from hogs	4		
Grapes	1	Revoke	Not being supported for reregistration.
Guavas	1	Revoke	Not being supported for reregistration.
Mangoes	1	Revoke	Not being supported for reregistration.
Melons	3	Revoke	Not being supported for reregistration.
Mushrooms	3	Revoke	Not being supported for reregistration.
Nectarines	1	Revoke	Not being supported for reregistration.
Okra	1	Revoke	Not being supported for reregistration.
Onions (dry bulb only)	1	Revoke	Not being supported for reregistration.
Peaches	1	Revoke	Not being supported for reregistration.
Pears	1	Revoke	Not being supported for reregistration.
Pecans	0.01	Revoke	Not being supported for reregistration.
Peppers	1	Revoke	Not being supported for reregistration.
Pineapple	1	Revoke	Not being supported for reregistration.
Plums (fresh prunes)	1	Revoke	Not being supported for reregistration.

Table B (continued).

Commodity	Tolerance Listed Under 40 CFR (ppm)	Reassessed Tolerance (ppm)	Comment [Correct Commodity Definition]
Pumpkins	3	Revoke	Not being supported for reregistration.
Quinces	1	Revoke	Not being supported for reregistration.
Squash	3	Revoke	Not being supported for reregistration.
Strawberries	1	Revoke	Not being supported for reregistration.
Summer squash	3	Revoke	Not being supported for reregistration.
Tomatoes	3	Revoke	Not being supported for reregistration.
Tolerance To Be Proposed Under 40 CFR §180.133			
Barley, grain	None established	TBD	A nature of the residue study for lindane residues resulting from seed treatment application to a cereal grain is required.
Barley, hay		TBD	
Barley, straw		TBD	
Canola, seed		TBD	
Corn, grain		TBD	
Corn, forage		TBD	
Corn, stover		TBD	
Oat, grain		TBD	
Oat, forage		TBD	
Oat, hay		TBD	
Oat, straw		TBD	
Rape greens		TBD	
Rye, grain		TBD	
Rye, forage		TBD	
Rye, straw		TBD	
Sorghum, grain		TBD	
Sorghum, forage		TBD	
Sorghum, stover		TBD	
Wheat, grain		TBD	
Wheat, forage		TBD	
Wheat, hay		TBD	
Wheat, straw		TBD	

TBD = To be determined.

CODEX HARMONIZATION

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for lindane in/on various plant and animal commodities. The Codex MRLs are expressed in terms of gamma HCH (fat-soluble). With respect to tolerance expression, the Codex MRL and U.S. tolerance for lindane are presently in harmony. However, the nature of the residue in plants and ruminants remains inadequately understood, and the HED's MARC may determine that additional lindane metabolites should be included in the U.S. tolerance expression.

A numerical comparison of the Codex MRLs and the corresponding **reassessed** U.S. tolerances resulting from seed treatment is presented in Table C. The established Codex MRLs and the recommended U.S. tolerances for Brussels sprouts, cabbage (Savoy), cabbages (head), cereal grains, lettuce (head), and radish are not in harmony presumably because of differences in good agricultural practices. Attempts to harmonize residue limits in animal commodities cannot be made at this time because of several residue chemistry data gaps.

Table C. Codex MRLs and applicable U.S. tolerances for lindane. Recommendations are based on conclusions following reassessment of U.S. tolerances (see Table B).

Codex		Reassessed U.S. Tolerance, ppm ¹	Codex Comments
Commodity, As Defined	MRL in mg/kg (Step)		
Apple	0.5 (CXL)	Revoke	Not being supported for reregistration.
Beans (dry)	1 (CXL) ²	None established	Not being supported for reregistration.
Brussels sprouts	0.5 (CXL)	Revoke	Not being supported for reregistration.
Cabbage, Savoy	0.5 (CXL)	Revoke	Not being supported for reregistration.
Cabbages, Head	0.5 (CXL)	Revoke	Not being supported for reregistration.
Cacao beans	1 (CXL)	None established	Not being supported for reregistration.
Carrot	0.2 (CXL)	None established	Not being supported for reregistration.
Cauliflower	0.5 (CXL)	Revoke	Not being supported for reregistration.
Cereal grains	0.5 (CXL) ²	TBD for the grains of barley, oats, rye, and wheat	
Cherries	0.5 (CXL)	Revoke	Not being supported for reregistration.
Cocoa butter	1 (CXL)	None established	Not being supported for reregistration.
Cocoa mass	1 (CXL)	None established	Not being supported for reregistration.
Cranberry	3 (CXL)	None established	Not being supported for reregistration.
Currant, Red, White	0.5 (CXL)	None established	Not being supported for reregistration.
Eggs	0.1 (CXL)	None established	
Endive	2 (CXL)	None established	Not being supported for reregistration.
Grapes	0.5 (CXL)	Revoke	Not being supported for reregistration.
Kohlrabi	1 (CXL)	Revoke	Not being supported for reregistration.
Lettuce, Head	2 (CXL)	Revoke	Not being supported for reregistration.
Meat of cattle, pigs, and sheep	2 (CXL)	To be determined (TBD)	
Milks	0.1 (CXL)	None established	
Pear	0.5 (CXL)	Revoke	Not being supported for reregistration.
Peas (pods and succulent = immature seeds)	0.1 (CXL)	None established	Not being supported for reregistration.
Plums (including prunes)	0.5 (CXL)	Revoke	Not being supported for reregistration.
Potato	0.05 (CXL)	None established	Not being supported for reregistration.
Poultry meat	0.7 (CXL)	None established	
Radish	1 (CXL)	Revoke	Not being supported for reregistration.
Rape seed	0.05 (CXL)	None established	
Spinach	2 (CXL)	Revoke	Not being supported for reregistration.

Codex		Reassessed U.S. Tolerance, ppm ¹	Codex Comments
Commodity, As Defined	MRL in mg/kg (Step)		
Strawberry	3 (CXL)	Revoke	Not being supported for reregistration.
Sugar beet	0.1 (CXL)	None established	Not being supported for reregistration.
Sugar beet leaves or tops	0.1 CXL)	None established	Not being supported for reregistration.
Tomato	2 (CXL)	Revoke	Not being supported for reregistration.

¹ Reassessed U.S. tolerances pending compliance by the registrants with the recommendations specified in “GLN 860.1200: Directions for Use” section of this Chapter.

² Postharvest treatment of the commodity.

TBD = To be determined.

DIETARY EXPOSURE ASSESSMENT

Anticipated residues of lindane were recently determined by HED (DP Barcode D279260, T. Morton, 12/4/01) using data from available plant and animal metabolism studies along with animal feeding studies.

AGENCY MEMORANDA RELEVANT TO REREGISTRATION

CB No.: 3257
Subject: ID No. 359-686. Lindane Registration Standard Followup. Analytical Methods for Plants
From: N. Dodd
To: A. Rispin, G. LaRocca, and E. Budd
Dated: 3/24/88
MRID(s): 40431202 and 40431206

CB No.: 3259
Subject: ID No. 359-686. Lindane Registration Standard Followup - Residues From Seed Treatment
From: N. Dodd
To: A. Rispin, G. LaRocca, and E. Budd
Dated: 3/24/88
MRID(s): 40431207

CB No: 3260
Subject: Lindane Registration Standard Follow up. Storage stability.
From: N. Dodd
To: A. Rispin, G. LaRocca, and E. Budd
Dated: 3/24/88
MRIDs: 40431203 and 40431205

CB No: 3261
Subject: Lindane Registration Standard Follow up - Analytical Methods for Animal Tissues, Eggs, and Milk.
From: N. Dodd
To: A. Rispin, G. LaRocca, and E. Budd
Dated: 3/24/88
MRID: 40431208

CB No. 3267
Subject: Partial Response (November 10, 1987) by Centre International d'Etudes du Lindane (CIEL) to Data Gap 171-4 (Nature of the Residue in Plants as Identified in the Residue Chemistry Chapter of the September 30, 1985 Lindane Registration Standard)
From: G. Otakie
To: A. Rispin, G. LaRocca, and E. Budd
Dated: 3/24/88
MRID(s): 40410902, 40431201, and 40431204

CB No: 3312
Subject: Partial Response (7/21/87) by Centre International d'Etudes du Lindane (CIEL) to Data Gap 171-4 (Nature of the Residue in Livestock Ruminants) as Identified in the Residue Chemistry Chapter of the September 30, 1985 Lindane Registration Standard.
From: C. Deyrup
To: A. Rispin, G. LaRocca, and E. Budd
Dated: 3/24/88
MRID: 40271302

DEB No. 3315
Subject: Partial Response (July 15, 1987) by Centre International d'Etudes du Lindane (CIEL) to Data Gap 171-4 (Nature of the Residue in Livestock Poultry) as Identified in the Residue Chemistry Chapter of the September 30, 1985 Lindane Registration Standard
From: J. Onley
To: A. Rispin, G. LaRocca, and E. Budd
Dated: 3/24/88
MRID(s): 40271301

CB No: 4035
Subject: ID No. 52904-C. Lindane Registration Standard Followup. Storage Stability Data.
From: S. Willett
To: R. Engler, G. LaRocca, and E. Budd
Dated: 8/23/88 and 8/26/88 (addendum)
MRID: 40660502

CB No: 4034
Subject: Partial Response (June 9, 1988) by Centre International d'Etudes du Lindane (CIEL) to Data Gap Section 171-4 (Magnitude of the Residue in Poultry and Eggs) as Identified in the Residue Chemistry Chapter of the September 30, 1985 Lindane Registration Standard.
From: G. Otakie
To: R. Engler, G. LaRocca, and E. Budd
Dated: 8/31/88
MRID: 40660501

CB No.: 4038
Subject: ID No. 52904-C. Lindane Registration Standard Followup. Residues in Swine
From: S. Willett
To: R. Engler, G. LaRocca, and E. Budd
Dated: 8/29/88
MRID(s): 40660504

CB No.: 4036
Subject: Partial Response (April 7, 1988) by Centre International d'Etudes du Lindane (CIEL) to Data Gap Section 171-4 [Magnitude of Residue in Animals (Sheep)] as Identified in the Residue Chemistry Chapter of the September 30, 1985 Lindane Registration Standard.
From: M. Kovacs
To: R. Engler, G. LaRocca, and E. Budd
Dated: 8/31/88
MRID(s): 40660503

CB No.: 4037
Subject: Partial Response (December 15, 1987) by Centre International d'Etudes du Lindane (CIEL) to Data Gap 171-4 [Magnitude of Residue in Animals (Dairy Cattle Meat and Milk)] as Identified in the Residue Chemistry Chapter of the September 30, 1985 Lindane Registration Standard
From: M. Kovacs
To: R. Engler, G. LaRocca, E. Budd
Dated: 9/20/88
MRID(s): 40660505

CB No.: 7470
Subject: Rhone-Poulenc AG Company: Response to the Lindane Reregistration Standard: Crop field Trials and Storage Stability Data
From: R. Perfetti
To: R. Engler and L. Rossi
Dated: 3/29/91
MRID: 41699701

CB No. 8075
DP Barcode: D164898
Subject: CIEL: Response to the Lindane Reregistration Standard: Residue and Processing Data
From: R. Perfetti
To: W. Burnam and L. Rossi
Dated: 4/8/92
MRID: 41861201 and 41861202

CB No. 15325
DP Barcode: D213401
Subject: Lindane (Case 0315, Chemical 009001, List A). Seed Treatment Uses.
From: S. Funk
To: L. Schnaubelt/R. Richards
Dated: 10/31/95
MRID: None

DP Barcode: D239699
Subject: Lindane (Chemical 009001, List A): CIEL Submissions to Upgrade Plant Analytical Method, Nature of the Residue in/on Cucumbers, Nature of the Residue in/on Apples. Time Extension Request for Ruminant Feeding Study, Ruminant Commodity Storage Stability Study, and Ruminant Commodity Analytical Method Study.
From: S. Funk
To: S. Jennings/W. Waldrop
Dated: 12/16/97
MRID(s): 44383001 through 44383004

DP Barcode: D240495
Subject: Lindane (009001): Nature of the Residue in Spinach and Poultry (GLN 860.1300).
From: T. Morton
To: M. McDavit/B. Shackleford
Dated: 12/14/99
MRID(s): 44405403 and 44405404

DP Barcode: D242510
Subject: Lindane (009001): Nature of the Residue in Plants and Animals (GLN 860.1300), Storage Stability (GLN 860.1380), Residue Analytical Method (GLN 860.1340), and Meat, Milk, Poultry, Eggs (GLN 860.1480).
From: T. Morton
To: M. McDavit/B. Shackleford
Dated: 12/14/99
MRID(s): 44440601, 44440602, 44440603, and 44440604.

DP Barcode: D257805
 Subject: Lindane (009001): Nature of the Residue in Livestock (GLN 860.1300), Residue Analytical Method (GLN 860.1340), and Storage Stability (GLN 860.1380).
 From: T. Morton
 To: M. McDavit/B. Shackleford
 Dated: 12/14/99
 MRID(s): 44867104, 44867105, and 44867106

DP Barcode: D259318
 Subject: Lindane (009001): Magnitude of the Residue in/on Wheat
 From: T. Morton
 To: M. Howard/B. Shackleford
 Dated: 8/30/00
 MRID(s): 44909901

DP Barcode: D254236 and D265919
 Subject: PP#9F05057. Lindane (009001): Time Limited Tolerances for Various Crops.
 From: T. Morton
 To: M. Howard/B. Shackleford
 Dated: 8/30/00
 MRID(s): None

DP Barcode: D172626 and D198353
 Subject: Lindane: Confined Rotational Crop Study.
 From: T. Morton
 To: M. Howard/B. Shackleford
 Dated: 8/30/00
 MRID(s): 41967301

DP Barcode: D269094
 Subject: Lindane (009001): Waiver Request for Nature of the Residue in Plants Grown From Seed Treated With Lindane (GLN 860.1300).
 From: T. Morton
 To: M. Howard/B. Shackleford
 Dated: 1/9/01
 MRID(s): None

DP Barcode: D272625
 Subject: Lindane (009001): Clarification on Waiver Request for Nature of the Residue in Plants Grown From Seed Treated With Lindane (GLN 860.1300).
 From: T. Morton
 To: M. Howard/B. Shackleford
 Dated: 2/13/01
 MRID(s): None

DP Barcode: D243547
 Subject: Lindane (009001): Question on Applicability of Seed Treatment Data for Pre-Plant Soil Treatment Uses.
 From: T. Morton
 To: M. Howard/B. Shackleford
 Dated: 2/28/01
 MRID(s): None

DP Barcode: D244798
Subject: Lindane (009001): Status on Residue Chemistry Requirements for Lindane Seed Treatment Uses.
From: T. Morton
To: M. Howard/B. Shackleford
Dated: 3/13/01
MRID(s): None

DP Barcode: D258079
Subject: Lindane (009001): Magnitude of the Residue in Meat and Milk of Dairy Cattle (GLN 860.1480).
From: T. Morton
To: M. Howard/B. Shackleford
Dated: 3/13/01
MRID(s): 44877501

DP Barcode: D269388 and D273830
Subject: PP#9F6022 Lindane (009001): Lindane in/on Canola.
From: T. Morton
To: M. Howard/B. Shackleford
Dated: 5/10/01
MRID(s): 44864401 and 45310501

DP Barcode: D271442 and D274158
Subject: Lindane: Nature of the Residue in Livestock.
From: T. Morton
To: M. Howard/B. Shackleford
Dated: 4/18/01
MRID(s): 45224101, 45224102, 45277201

DP Barcode: D274313
Subject: Lindane (009001): Magnitude of the Residue in Wheat.
From: T. Morton
To: M. Howard/B. Shackleford
Dated: 5/10/01
MRID(s): 45330301

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